



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/807,449	03/24/2004	Karin Jooss	3802-090-27 CIP	3354
29585	7590	11/25/2009		
DLA PIPER US LLP 153 TOWNSEND STREET SUITE 800 SAN FRANCISCO, CA 94107-1957			EXAMINER Ouspenski, ILIA I	
			ART UNIT 1644	PAPER NUMBER
			NOTIFICATION DATE 11/25/2009	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PatentDocketingUS-PaloAlto@dlapiper.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/807,449	<b>Applicant(s)</b> JOOSS ET AL.	
	<b>Examiner</b> ILIA OUSPENSKI	<b>Art Unit</b> 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 September 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-43 is/are pending in the application.
- 4a) Of the above claim(s) 3,5,9,12-18,21,22 and 25-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4,6-8,10,11,19,20,23 and 24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>09/04/2009</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

1. Applicant's amendment and remarks filed on 09/04/2009 are acknowledged.

Claims 1 and 3 – 43 are pending.

Claims 3, 5, 9, 12 – 18, 21 – 22, and 25 – 43 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected Inventions/Species, there being no allowable generic or linking claim. Applicant timely traversed the restriction requirement in the reply filed on 11/21/2006.

Claims 1, 4, 6 – 8, 10 – 11, 19 – 20, and 23 – 24 are presently under consideration, as they read on the elected invention and species.

2. The rejections of record have been withdrawn in view of Applicant's amendment and arguments, except as reiterated herein.

3. The following is a quotation of **35 U.S.C. 103(a)** which forms the basis for all obviousness rejections set forth in this Office action:

*(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.*

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1, 4, 6 – 8, 10 – 11, 19 – 20, and 23 – 24 are rejected under **35 U.S.C. 103(a)** as being unpatentable over Gri et al. (J. Immunol., 2003 (January), 170: 99 – 106; of record; see entire document) in view of Chen et al. (US Pat. Pub. No. 2003/0035790; of record; see entire document)

Gri et al. teach a method of treating colon carcinoma by administering cells of a carcinoma cell line (i.e. bystander cells) transduced to express GM-CSF and OX40 ligand (e.g. Results at page 101). Gri et al. further teach that OX40 ligand is functionally equivalent with anti-OX40 antibodies (e.g. page 105, last paragraph of Discussion). The reference further teaches that the GM-CSF-expressing cells are inactivated by irradiation (e.g. page 100, last full paragraph), and envisions using the method for human therapy (e.g. pages 99 – 100, bridging paragraph).

The reference differs from the instant claims in that it does not specifically exemplify administering anti-OX40 antibodies together with GM-CSF-expressing bystander tumor cells.

Chen et al. teach a method of treating cancer by administering a recombinant adenovirus engineered to express GM-CSF, and an anti-OX40 antibody (e.g. paragraphs 00341, 0117, 0120, and 0277). Chen et al. further teach GM-CSF may be

Art Unit: 1644

expressed in mammalian cells (e.g. paragraphs 0212 – 0214), and discuss a cancer vaccine approach, wherein cancer cells are isolated from patients, transduced in vitro, irradiated, and administered to patients (e.g. paragraph 0005). Chen et al. also teach that these methods can be applied to treating prostate cancer (e.g. claim 39).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to apply the teachings of Chen et al. regarding administration of anti-OX40 antibodies to enhance the immune response against GM-CSF-expressing tumor cells to those of Gri et al. to arrive at the instantly claimed method. One of ordinary skill in the art at the time the invention was made would have been motivated to do so, in view of the recognized need to improve cancer immunotherapy, and have a reasonable expectation of success, in view of the specific teachings of the two cited references.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

5. The nonstatutory **double patenting** rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

Art Unit: 1644

F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1, 4, 6 – 8, 10 – 11, 19 – 20, and 23 – 24 stand provisionally rejected on the ground of nonstatutory **obviousness-type double patenting** as being unpatentable over claims 1 – 33 of copending Application USSN 10/404,662, for the reasons of record.

Applicant's request that this rejection be held in abeyance is acknowledged.

The rejection is presently maintained for the reasons of record.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

**7. Conclusion: no claim is allowed.**

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILIA OUSPENSKI whose telephone number is (571)272-2920. The examiner can normally be reached on Monday-Friday 9 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram R. Shukla can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ILIA OUSPENSKI/  
ILIA OUSPENSKI, Ph.D.  
Primary Examiner  
Art Unit 1644

November 19, 2009